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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,142	10/10/2007	Robert Brunham	APL-03-03-US	9228
7590 Patrick J Halloran 3141 Muirfield Rd Center Valley, PA 18034				
EXAMINER				
OGUNBIYL, OLUWATOSIN A				
ART UNIT		PAPER NUMBER		
1645				
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11/10/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/580,142

**Applicant(s)**

BRUNHAM ET AL.

**Examiner**

OLUWATOSIN OGUNBIYI

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-38 are pending in the application.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, 20, 21, 22, 24, 30, 37 drawn to an isolated and purified nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any one of: (a) SEQ ID No: 2; (b) SEQ ID No: 4; (c) SEQ ID No: 6; (d) SEQ ID No: 8; (e) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a) to (d); and (f) a polypeptide of (a), (b), (c) or (d) which has been modified by conservative amino acid substitution without loss of immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a), (b), (c) or (d).

Group II, claim(s) 16-19, drawn to a method for preventing or treating *Chlamydia* infection comprising the step of administering an effective amount of a nucleic acid molecule which encodes a polypeptide selected from any one of: (a) SEQ ID No: 2; (b) SEQ ID No: 4; (c) SEQ ID No: 6; (d) SEQ ID No: 8; (e) an immunogenic fragment comprising at least 100 consecutive amino acids from the polypeptide of (a) to (d); and (f) a polypeptide of any one of (a) to (e) which

has been modified by conservative amino acid substitution without loss of immunogenicity, wherein said modified polypeptide is at least 90% identical in amino acid sequence to the corresponding polypeptide of any one of (a) to (e); wherein the nucleic acid molecule is operatively linked to one or more control sequences for expression of the polypeptide..

Group III, claim(s) 23, 26-29, 31-37, drawn to a polypeptide encoded by a nucleic acid sequence according to any one of claims 1, 2 and 4 to 7.

Group IV, claim(s) 25, drawn to an antibody against the polypeptide of any one of claims 24.

Group V, claim(s) 26-29, drawn to a vaccine comprising at least one first polypeptide according to any one of claims 1, 4, to 7 and a pharmaceutically acceptable carrier, optionally comprising a second polypeptide which enhances the immune response to the first polypeptide.

Group VI, claim(s) 38, drawn to a method for preventing or treating *Chlamydia* infection comprising the step of administering an effective amount of a polypeptide selected from any one of: (a) SEQ ID No: 2; (b) SEQ ID No: 4; (c) SEQ ID No: 6; (d) SEQ ID No. 8; (e) an immunogenic fragment comprising at least 100 consecutive amino acids from the polypeptide of (a) to (d); and (f) a polypeptide of any one of (a) to (e) which has been modified by conservative amino acid substitution without loss of immunogenicity; wherein said modified polypeptide is at least 90% identical in amino acid sequence to the corresponding polypeptide of any one of (a) to (e).

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-VI lack unity of invention because even though the inventions of these groups require the technical feature of a Mgp002 protein (see specification example 1), this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Grandi et al (WO03/049762) published June 19, 2003. Grandi et al teaches a Mgp002 protein i.e. SEQ ID NO: 27 (and corresponding nucleic acid molecule SEQ ID NO: 28) that is 100 % identical to the instant Mgp002 protein SEQ ID NO: 4 and teaches the nucleotide acid molecule comprising a nucleotide sequence encoding said Mgp002 protein. The Mgp002 protein of Grandi et al comprises an immunogenic fragment comprising at least 12 consecutive amino acids of SEQ ID NO: 2 or SEQ ID NO: 4 or SEQ ID NO: 6. Also said polypeptide of Grandi et al has been modified by conservative amino acid substitutions and is at least 75% identical in amino acid sequence to SEQ ID NO: 2. See attached sequence alignments.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/  
Examiner, Art Unit 1645

/Patricia A. Duffy/  
Primary Examiner, Art Unit 1645

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